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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,870	11/02/2001	H. George Brennan	01BRE1	5039

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EXAMINER

SNAY, JEFFREY R

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/008,870

Applicant(s)

BRENNAN, H. GEORGE

Examiner

Jeffrey R. Snay

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date, ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "visualization means" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. Claims 3-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, applicant invokes 35 USC 112, 6th paragraph by reciting a means plus function element. The present use of means plus function language renders the claim indefinite for two reasons. First, each of claims 3 and 4 constitutes a single means claim because no other elements are recited. These claims are therefore per se indefinite for being of indeterminate scope. See MPEP 2164.08(a). Second, application of 35 USC 112, 6th paragraph, requires that the means encompassed by the claim is limited to that structure specifically identified by the specification and any functional equivalents thereof. However, the instant specification fails to disclose any structure to exemplify the recited means for indicating exposure. The means plus function language is therefore of indeterminate scope.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Karow et al (WO 99/55404).

It is noted that specific reference to columns and lines of Karow et al are made in reference to U.S. Patent 6,626,172 as an english language equivalent to the

Art Unit: 1743

international patent document. But the international patent forms the basis for this rejection.

Karow et al disclose a nasal dilator which includes at least one diagnostic agents thereon. The device is disclosed as being constructed for insertion into the nasal passage of an individual in order to both increase the flow of respiratory air by dilating the passage and to carry out diagnostic reactions or tests (column 2, lines 38-51). The device includes to mirror image, U-shaped sections which conform to the inner wall of each nasal cavity, and an orthogonal connecting section which crosses the septum when in position (see Figure 7). The U-shaped sections are disclosed in one embodiment as being slightly arched in an unstressed state (hence, U-shaped) (see column 4, lines 44-45). The inner surface (10) is in contact with the flow of respiratory air (column 4, lines 66-67) and both the outer and inner surfaces can have applied thereon at least one diagnostic agent (column 3, lines 7-10). Examples of such diagnostic agents include antigens with specific receptivity to particular antibodies.

With respect to instant claims 3 and 4, reference is made to the rejection, supra, of these claims for indefiniteness. To the extent that the claims appear to recite a mechanism for analysis of the nasal diagnostic device, such a mechanism is disclosed by Karow et al in the form of an enzymatic or radiological immunoassay (column 3, lines 45-50).

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Petruson discloses a nasal dilator of similar structure to the

Art Unit: 1743

claimed device. Reznick discloses a device which is inserted into a nasal cavity and includes the capability of absorbing particulate, chemical, molecular or organic matter (column 4, lines 36 et seq). Pannwitz teaches generally the concept of wearable air sampling devices for detecting airborne contaminants. Similarly, each of Flaherty et al, Manning et al, and Adams et al disclose different devices for collecting and monitoring respiratory air for detection of airborne contaminants.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Snay whose telephone number is (571) 272-1264. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey R. Snay
Primary Examiner
Art Unit 1743